

DISPOSITION: July 28, 1954. Default decree of condemnation and destruction.

**4429. Misbranding of glandular products. U. S. v. 40 Vials, etc. (F. D. C. No. 36805. Sample Nos. 90071-L to 90077-L, incl., 90079-L.)**

**LIBEL FILED:** On or about June 1, 1954, Western District of Missouri.

**ALLEGED SHIPMENT:** On or about August 2, 1951, November 28, 1952, November 16, 1953, and March 14 and 23, 1954, from Chicago, Ill.

**PRODUCT:** 40 vials of *pituitary anterior aqueous extract*, 60 vials of *ovarian aqueous extract*, 56 vials of *pituitary anterior and ovarian solution*, 20 vials of *orchic tissue aqueous extract*, 45 vials of *pituitary anterior and orchic solution*, 19 vials of *pituitary whole aqueous extract*, 52 vials of *ovarian residue aqueous extract*, and 74 vials of *Spleenæ solution* at Kansas City, Mo., in possession of Henry C. Haist & Co., Inc. The size of each vial was 30 cc.

**RESULTS OF INVESTIGATION:** The products were shipped in bulk from Chicago, Ill., and upon receipt by the consignee, were repackaged and relabeled.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

**4430. Misbranding of aqueous extract of anterior pituitary. U. S. v. 698 Vials \* \* \*. (F. D. C. No. 37023. Sample Nos. 61672-L to 61674-L, incl.)**

**LIBEL FILED:** On or about August 3, 1954, Western District of Missouri.

**ALLEGED SHIPMENT:** On or about February 17 and March 17, 1953, from Chicago, Ill.

**PRODUCT:** 698 vials of *aqueous extract of anterior pituitary* at Kansas City, Mo., in possession of Ashe Lockhart, Inc. Some of the vials were labeled and some were unlabeled.

**RESULTS OF INVESTIGATION:** The article had been shipped in bulk from Chicago, Ill., and after its receipt by the consignee, was repackaged into vials.

**LABEL, IN PART:** (Vial) "10 c. c. Aqueous Extract Of Anterior Pituitary Each c. c. contains water soluble extractives from 18½ grains fresh tissue. Contains .5% Chlorobutanol (Chloroform Derivative). \* \* \* Distributed by Ashe Lockhart, Inc. Kansas City, Mo."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from such requirement. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 8, 1954. Default decree of destruction.

**4431. Misbranding of orchic substance. U. S. v. 1 Canister, etc. (F. D. C. No. 36818. Sample No. 84853-L.)**

**LIBEL FILED:** June 7, 1954, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about September 23, 1953, and March 1, 1954, from Chicago, Ill.

**PRODUCT:** 1 5-pound canister of *orchic substance in powder form* and 3 bottles containing *orchic substance in capsules* at Philadelphia, Pa., in possession of Fred F. Wanner & Sons.

**RESULTS OF INVESTIGATION:** The product, when shipped from Chicago, Ill., was in powder form and packaged in canisters. After receipt of the product by

the consignee, a portion was encapsulated and repackaged by the consignee into bottles.

**LABEL, IN PART:** (Bottle) "Capsules Orchic Substance Desiccated 10 Grains Average Dose Four to Six capsules daily. Caution—To be used only by or on the prescription of a physician Manufactured by Fred F. Wanner & Sons Philadelphia, Pa."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article in the canisters and in the bottles, namely, the label applied to the encapsulated powder, failed to bear adequate directions for use. The article was misbranded while held for sale after shipment in interstate commerce.

**DISPOSITION:** August 4, 1954. Default decree of condemnation and destruction.

### DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

#### 4432. Adulteration and misbranding of solution procaine with epinephrine.

U. S. v. 25 Boxes \* \* \*. (F. D. C. No. 36415. Sample No. 65385-L.)

**LIBEL FILED:** March 2, 1954, District of Minnesota.

**ALLEGED SHIPMENT:** Sometime prior to 1952, from Woodworth, Wis.

**PRODUCT:** 25 boxes, each containing 100 ampuls of *solution procaine with epinephrine* at Minneapolis, Minn.

**NATURE OF CHARGE:** Adulteration, Section 501 (b), the article purported to be and was represented as "Procaine Hydrochloride and Epinephrine Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the official standard since it contained less than 95 percent of the labeled amount of procaine hydrochloride and had a pH lower than 3.3.

Misbranding, Section 502 (a), the label statement "Each 1 cc. Contains Procaine Hydrochloride U. S. P. (2%) . . . 0.02 gm." was false and misleading as applied to the article, which contained less than 0.02 gram of procaine hydrochloride per 1 cc..

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

**DISPOSITION:** June 23, 1954. Default decree of destruction.

#### 4433. Adulteration and misbranding of tincture thimerosal. U. S. v. 69 Bottles \* \* \*. (F. D. C. No. 36688. Sample No. 70900-L.)

**LIBEL FILED:** March 16, 1954, Southern District of Indiana.

**ALLEGED SHIPMENT:** On or about August 28, 1952, by Ransdell Co., Inc., from Louisville, Ky.

**PRODUCT:** 69 bottles of *tincture thimerosal* at Indianapolis, Ind. Analysis showed that the product contained 75 percent of the declared amount of thimerosal.

**LABEL, IN PART:** "One Gallon 3.78 Liters Tincture Thimerosal, N. N. R. 1:1000 Sodium Ethyl Mercuri Thiosalicylate (Thimerosal, N. F.) \* \* \* Thimerosal, N. F. 0.1% \* \* \* For External Use Only \* \* \* Interstate Drug Company."

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\*See also No. 4423.